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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,615	06/01/2001	Mark A. Brudnak		2272

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EXAMINER	
PRATS, FRANCISCO CHANDLER	
ART UNIT	**PAPER NUMBER**
1651	17

DATE MAILED: 10/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,615	BRUDNAK, MARK A.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *3,4,9-11,16,23,26,34 and 35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-8,12-15,17-22,24,25 and 27-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed August 4, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 21-35 have been added.

Claims 1-35 are pending.

Election/Restrictions

Applicant's election of the species of composition comprising the ingredients galactose, acid-fast protease, peptidase, cysteine protease and phytase, in Paper No. 9, filed January 6, 2003, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

As indicated in the office action of March 5, 2003, claims 1, 2, 5-8, 12-15 and 17-20 were examined on the merits to the extent they read on the elected invention. As also indicated in the office action of March 5, 2003, the composition comprising the ingredients galactose, acid fast protease, peptidase, cysteine protease and phytase is considered to be free of the prior art.

As further indicated in the office action of March 5, 2003, the search and examination was extended to additional species recited in the claims. See MPEP § 803.02. In response to the office action of March 5, 2003, applicant amended the claims to significantly change the scope of the claimed invention, deleting a plurality of the originally present embodiments, said deletion including deleting embodiments rejected in the first office action as unpatentable over the prior art. Applicant's amendment also significantly changed the combinations of ingredients presented for examination, adding embodiments which were either not originally presented for examination, or which were not originally examined. Thus, as amended, the pending claims still contain a large number of patentably distinct species of inventions, each species reciting a different combination of ingredients. The species election requirement will therefore be maintained. See MPEP § 806.04(b).

Claims 3, 4, 9-11, 16, 23, 26, 34 and 35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species of compositions containing numerous different combinations of ingredients, there being no allowable generic or linking claim. As discussed above, election was made **without** traverse in Paper No. 9, filed January 6, 2003.

1, 2, 5-8, 12-15, 17-22, 24, 25, and 27-33 are examined on the merits.

Specification

The preliminary amendments filed December 4, 2001, and August 4, 2003, are objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

- the insertion at page 4, line 25;
- the insertion at page 6, line 26;
- the insertion at page 7, line 2.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5-8, 12-15, 17-22, 24, 25, and 27-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, the as-filed specification fails to provide support for the new recitation "material that upon ingestion by a human suffering from autism affects expression of an endogenously produced gene product that cleaves proline containing peptides in such a manner as to relieve symptoms of autism". The new claim language encompasses materials which ***by themselves*** act to affect the expression of the designated peptidase. It is noted that the specification states that galactose, fructose, lactose, sucrose and glucose might act to affect expression of the designated peptidase so as to alleviate autism. However, the specification provides no direct evidence that these sugars by themselves act in the hypothesized manner. In fact the entire effect of the sugars by themselves is hypothesized, and unsupported by direct evidence. The only

effective composition disclosed by applicant contains 5 ingredients in addition to the galactose. See specification at pages 10 and 11. In view of the total lack of evidence that the asserted sugars by themselves act to affect peptidase gene-expression so as to alleviate the symptoms of autism, it is clear that applicant was not in possession of the presently claimed subject matter when the application was filed.

Moreover, the claim recitation at issue encompasses any and all substances which affect the expression of the recited gene product. Despite the enormous scope of the recitation, other than the sugars discussed above, applicant does not provide any structures or other guidance, such as concrete examples, wherein the claimed gene expression-affecting materials are described. It is therefore clear that applicant did not have in his possession the claimed subject matter at the time the application was filed. A holding of lack of written description is therefore required.

Claims 1, 2, 5-8, 12-15, 17-22, 24, 25, and 27-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it

pertains, or with which it is most nearly connected, to make and/or use the invention.

As discussed above, the new recitation "material that upon ingestion by a human suffering from autism affects expression of an endogenously produced gene product that cleaves proline containing peptides in such a manner as to relieve symptoms of autism" is considered to lack written support in the specification as originally filed. The specification as filed also does not provide an enabling disclosure for the new language. As discussed above, applicant has presented no direct evidence that the asserted sugars will act to alleviate the symptoms of autism. In fact, the language of the specification itself suggests that applicant is not sure about the therapeutic efficacy. See specification at page 15, lines 8-11. It is again pointed out that the only composition found to be effective contains 5 ingredients in addition to the galactose.

Moreover, autism has long been studied and been found difficult to treat, and can therefore be considered a very unpredictable field. The enormous breadth of the present claim language encompassing literally any material in the universe, combined with the unpredictability inherent in determining therapeutic efficacy in autism, clearly means that the skilled artisan would have to undertake an essentially trial and error

process to determine a suitable peptidase expression-affecting, autism-treating material. In view of the lack of any clear guidance from the specification as to the direction this trial and error process must take with respect to suitable compounds, such a trial and error process must be considered undue experimentation. In sum, because of the lack of clear experimental evidence and guidance in the specification, it is clear that the specification does not provide an enabling disclosure for the new recitation "material that upon ingestion by a human suffering from autism affects expression of an endogenously produced gene product that cleaves proline containing peptides in such a manner as to relieve symptoms of autism". A holding of non-enablement is therefore required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United

States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 5-7 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Wilkinson et al (U.S. Pat. 6,251,391 B1).

Wilkinson describes a composition comprising casomorphinase (dipeptidyl petidase IV) activity, said composition including peptidase FP II, acid-stable protease, papain and lysine. See column 12, line 39 through column 13, line 54. Thus, the described composition contains the enzyme activities required by the rejected claims. Moreover, the ingredient lysine is described as providing a more alkaline environment so as to increase the enzymatic activity of the composition. Because the lysine increases the activity of enzymes, the lysine ingredient can be considered to be the claim peptidase expression-increasing ingredient.

Moreover, Wilkinson discloses various suitable additives to the disclosed compositions, including dextrose (i.e., glucose) and maltodextrin. See column 9, lines 4-20. In view of the fact that glucose is explicitly disclosed by applicant as a suitable peptidase expression-increasing ingredient (specification, page 15, lines 1-19), Wilkinson's use of dextrose as a carrier is considered to anticipate the claimed

requirement of a peptidase-activating sugar. A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

Claims 1, 2 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilkinson et al (U.S. Pat. 6,251,391 B1).

As discussed above, Wilkinson describes describes a composition comprising casomorphinase (dipeptidyl petidase IV) activity, said composition including peptidase FP II, acid-stable protease, papain and lysine, and is therefore considered to anticipate claims 1 and 5-7. As also discussed above, Wilkinson also describes that glucose may be used as a carrier for the compositions.

Wilkinson differs from the claims in that Wilkinson does not describe the use of galactose in the composition. However, the claimed substitution of galactose for glucose in the composition of Wilkinson must be considered the substitution of one well known pharmaceutically acceptable monosaccharide carrier compound for another, and therefore obvious under § 103(a). A holding of obviousness is clearly required.

Claims 1, 2, 5-8, 12-15, 17-22, 24, 25, and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over De Lima et al WO 97/39116.

De Lima discloses that animal feed compositions suitably contain combinations of phytases and proteases, as recited in applicant's claims. See page 33, lines 4 and 5. De Lima also discloses that suitable protease compositions contain peptidase activity, and include acid proteases such as trypsin. See page 28, lines 26, 27 and 32. Thus, De Lima differs from the claims under examination in that De Lima does not disclose the use of a peptidase having precisely the same activity as that recited in applicant's claims. However, in view of the fact that the artisan of ordinary skill clearly would have considered a peptidase known to have the claimed activity suitable in the compositions of De Lima, the artisan of ordinary skill clearly would have been motivated to have added those peptidases to a phytase-containing animal feed composition as disclosed by De Lima.

Moreover, De Lima discloses that binders suitable for use in the disclosed compositions include monosaccharide binders as well as oligosaccharide binders. See page 15, lines 12-24. Thus, the claimed use of the known food-safe monosaccharides galactose and/or glucose in the feed compositions of De Lima

must be considered obvious under § 103(a). Further still, with respect to those claims requiring glucans, note specifically that starch is a glucan, and that starch is a preferred compound for use in the core of the enzyme-containing granules disclosed by De Lima. See page 11, lines 4-7. In sum, because the prior art discloses the desirability of combining the claimed ingredients, a holding of obviousness under § 103(a) is clearly required.

Response to Arguments

In view of applicant's amendment significantly changing the scope and content of the embodiments presented for examination, different rejections than those made in the original office action are now required. Thus, while most of applicant's argument is not directed to the grounds of rejection set forth herein, applicant's argument has been fully considered to the extent applicable to the new grounds of rejection.

In response to the new matter objection, applicant requests withdrawal of the insertions asserted as having new matter. This is improper for several reasons. First, any amendment must be made according to the rules set forth at 37 CFR § 1.121. Applicant's request for withdrawal does not comply with these rules. An insertion cannot simply be withdrawn. The

application must be amended in accordance with the prescribed rules.

Second, the request for withdrawal contradicts applicant's own instructions in the amendment filed August 4, 2003. That is, in the submission filed August 4, 2003, applicant requests withdrawal of the insertion at page 4, line 25, yet in the same submission provides a new version of the same passage. Thus, it is not clear whether applicant desires to revert to the originally filed language, or the language filed on August 4, 2003.

Lastly, applicant is reminded that once an application is filed the disclosure therein cannot be changed so as to introduce any new matter whatsoever. For example, one cannot simply insert a citation to a publication if that citation was not present when the application was originally filed. Thus, the new citation to the Pangborn article is clearly improper.

With respect to the issue of obviousness, as discussed above, the Wilkinson disclosure makes it clear that the claimed combinations of ingredients, even if not anticipated by the prior art, clearly is rendered obvious by the prior art. Moreover, even discounting the disclosure of Wilkinson, the De Lima reference clearly discloses that the claimed combination of phytases and proteases, as well as peptidases, were suitable in

an animal feed composition. The selection of specific peptidases from among those known in the art must be considered obvious under § 103(a). Moreover, to the extent that applicant argues that the currently applied reference discloses a "laundry list" of enzymes suitable for use as food additives, it is respectfully pointed out applicant's specification similarly provides a laundry list of combinations of enzymes and ingredients for which a patentability determination must be made. In view of the specification's own admission (page 12, lines30-32) that the number of potential embodiments is exponential, and not all are "called out", it is suggested that applicant determine what applicant considers to be their actual invention, and limit prosecution to the actual product demonstrated as having therapeutic activity, rather than burdening administrative resources in a guessing game of determining what applicant considers to be their invention.

No claims are allowed. However, as discussed in the previous office action, claims directed to compositions comprising the ingredients galactose, acid fast protease, peptidase, cysteine protease and phytase are considered to be free of the prior art and would be allowable if rewritten

independent form, so as to overcome the rejection(s) under 35 U.S.C. § 112, set forth in this Office action.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on August 4, 2003, prompted the new ground(s) of rejection over the De Lima reference presented in this Office

action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the

organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP